

Message Text

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PAGE 01 PARIS 13340 051730Z

ACTION HEW-06

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TO SECSTATE WASHDC PRIORITY 2506

UNCLAS PARIS 13340

E.O. 11652: N/A

TAGS: ECEM, EIND, ETRD, PGOV, SWEL, TBIO, FR

SUBJECT: FRENCH REGULATIONS PERTAINING TO LIMITS FOR
ETHYLENE OXIDE (ETO) RESIDUES IN MEDICAL SUPPLIES AND
DEVICES

REF: STATE 080827

1. COPY OF SUBJECT REGULATION BEING POUCHED. IT WAS
PUBLISHED IN THE 9TH EDITION OF THE FRENCH
PHARMACOPEIA, WHICH CONCERNS REQUIREMENTS FOR
STERILIZATION BY ETHYLENE OXIDE, SUBSEQUENT CONTROLS,
MEASURING OF RESIDUAL GAS, AS WELL AS PRESERVATION AND
LABELING RULES, AND APPLIES TO ALL MEDICAL DEVICES
TREATED WITH ETHYLENE OXIDE. THIS REGULATION WAS
ESTABLISHED ON THE BASIS OF THE WORK OF SPECIALISTS IN
GAS ANALYSIS AND MICROBIOLOGY.

2. FRENCH PHARMACOPEIA HAS THE FORCE OF LAW AND
GOVERNS THE WHOLE PHARMACEUTICAL TRADE AT ALL LEVELS
FROM MANUFACTURING THROUGH DISTRIBUTION. IN THIS
CASE, THEREFORE, MEDICAL DEVICES STERILIZED WITH
ETHYLENE OXIDE CAN BE SOLD BY DRUGGISTS EXCLUSIVELY
IN COMPLIANCE WITH THE PHARMACOPEIA.

3. COMPLIANCE WITH THIS REGULATION IS THE
RESPONSIBILITY OF THE OFFICE OF PHARMACY INSPECTION,
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IN THE HEALTH MINISTRY. INSPECTORS VISIT PHARMACIES
REGULARLY AND OCCASIONALLY TAKE SAMPLES WHICH LATER
ARE ANALYZED AT THE NATIONAL HEALTH LABORATORY.

4. THE FRENCH MINISTRY OF HEALTH ALSO SENT THE
EMBASSY A COPY OF THE REPORT N THE RESEARCH DONE BY
SPECIALISTS IN GAS ANALYSIS AND MICROBIOLOGY WHICH

SERVED AS A BASIS FOR THIS REGULATION.

5. BOTH THIS REPORT AND THE REGULATION BASED ON IT
ARE BEING AIR-POUCHED TO THE DEPT FOR TRANSMITTAL TO
FDA.

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Message Attributes

Automatic Decaptioning: X
Capture Date: 01-Jan-1994 12:00:00 am
Channel Indicators: n/a
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Disposition Approved on Date:
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Disposition Comment:
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Disposition Event:
Disposition History: n/a
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